

APR 16 2002

Attachment 4

510(k) Summary

**Device  
Description**

Trade Name: H/S Catheter Set

Common Name: Hysterosalpingography or Hysterosonography Catheter

Classification Name: Cannula, manipulator/injector, Uterine, Product Code LKF

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**Predicate  
Device**

Modified Hysterosalpingography Set K953034, 8/29/95

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**Date**

March 13, 2002

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**Contact**

Richard Hettenbach  
Vice President, Regulatory Affairs and Quality Assurance  
Ackrad Laboratories, Inc.  
70 Jackson Drive  
Cranford, NJ 07016  
Tel: (908) 276-6390  
Fax: (908) 276-1895

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**Device  
Description**

The H/S Catheter Set can be used for conducting either Hysterosalpingography (examination of the uterus and fallopian tubes using x-rays) or Hysterosonography (examination of the uterus and fallopian tubes using ultrasound sonography). All components are provided sterile for single use only.

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**Technological  
Characteristics**

The H/S Catheter Set has the same technological characteristics as the predicate device. The intended use, operating principle are identical. The H/S Catheter Set incorporates the same product design and is packaged and sterilized using the same materials and processes.

**Performance  
Data**

Pre-clinical testing has been conducted to verify that the product meets the performance requirements described. It was determined that the H/S Catheter Set performs safely and effectively.

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**Conclusion**

The H/S Catheter Set is substantially equivalent to the predicate Modified Hysterosalpingography Set.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 16 2002

Mr. Richard Hettenbach  
Vice President, Regulatory Affairs  
and Quality Assurance  
Ackrad Laboratories  
70 Jackson Drive  
CRANFORD NJ 07016

Re: K020951  
Trade/Device Name: H/S Catheter Set,  
(5F) Model 61-5005, and (7F) Model 61-5007  
Regulation Number: None  
Regulatory Class: Unclassified  
Product Code: 85 LKF  
Dated: March 13, 2002  
Received: March 25, 2002

Dear Mr. Hettenbach:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

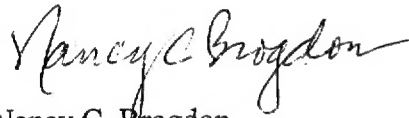
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Attachment 2

### Indications for Use Statement

510(k)  
Number

K020951

Device Name

H/S Catheter Set

Indications for  
Use

The H/S Catheter Set is used for the delivery of diagnostic contrast media agents in the female reproductive tract for examination of the uterus and fallopian tubes.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF  
NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒  
(Per 21 CFR 801.109)

OR

Over-The Counter Use ☐

*David L. Regan*  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K020951